

WHAT IS CLAIMED IS:

1. A lateral flow enzyme immunoassay device, comprising:
a sample pad comprising a slow lane and a fast lane separated by a hydrophobic barrier, wherein said slow lane contains an enzyme substrate and said fast lane contains an enzyme-antibody conjugate having affinity for an analyte;
a capture zone in fluid communication with said sample pad, said capture zone having a capture antibody incorporated therein having affinity for said analyte; and
an absorbent zone in fluid communication with said capture zone.
2. The immunoassay device of claim 1, wherein said analyte is selected from the group consisting of hormones, enzymes, lipoproteins, bacterial or viral antigens, immunoglobulins, lymphokines, cytokines, drugs and soluble cancer antigens.
3. The immunoassay device of claim 1, wherein said sample pad comprises high density polyethylene.
4. A flow-through lateral flow enzyme immunoassay device, comprising:
a disk comprising inner and outer hydrophilic zones separated by a hydrophobic barrier, said inner zone containing an enzyme substrate and having a smaller pore size than said outer zone, said outer zone containing an enzyme-antibody conjugate having affinity for an analyte;
a contact pad in fluid communication with said disk;
a capture zone in fluid communication with said contact pad; and
an absorbent zone in fluid communication with said contact pad.
5. A lateral flow enzyme immunoassay device, comprising:
a sample pad;
a label pad in fluid communication with said sample pad, said label pad containing an enzyme-antibody conjugate having affinity for an analyte;
a capture zone in fluid communication with said label pad, said capture zone containing a capture antibody having affinity for said analyte and an enzyme substrate at a test line.

6. The immunoassay device of claim 5, wherein said substrate is chemically immobilized at the test line.

7. The immunoassay device of claim 5, wherein said substrate is immobilized in a mordant under the test line.

8. The immunoassay device of claim 5, wherein said substrate is immobilized in a mordant dispensed within the test line.

9. The immunoassay device of claim 5, wherein said capture zone further comprises chemical groups incorporated therein, said chemical groups capable of specifically reacting with the product resulting from enzyme action on the substrate.

10. The immunoassay device of claim 9, wherein said chemical groups comprise diazotized amines.

11. A lateral flow enzyme immunoassay device, comprising:
a sample pad;
a label pad in fluid communication with said sample pad, said label pad containing a substrate covalently attached to a particle or imbibed within a sac, wherein said substrate-containing sac or particle is attached to an antibody;
a capture zone in fluid communication with said label pad, said capture zone containing an enzyme/mediator for releasing said substrate and a capture antibody at a test line; and
an absorbent zone in fluid communication with said capture zone.

12. The immunoassay device of claim 11, wherein said sac comprises a liposome.

13. The immunoassay device of claim 11, wherein said sac comprises an erythrocyte ghost.

14. The immunoassay device of claim 11, wherein said particle label comprises polyalkylcyanoacrylate polymer monosized colloids.

15. The immunoassay device of claim 11, wherein said enzyme/mediator is immobilized in a mordant within or under the test line.

16. The immunoassay device of claim 12, wherein said enzyme/mediator is attached to the capture antibody.

17. An enzyme immunoassay device, comprising:
a sample pad comprising a first lane containing a first barrier zone and a second lane containing a second barrier zone, wherein said first lane contains an enzyme-antibody conjugate having affinity for an analyte and said second lane contains an enzyme substrate, wherein said first barrier zone dissolves before said second barrier zone;
a capture zone in fluid communication with said sample pad, said capture zone containing a capture antibody incorporated therein having affinity for said analyte; and
an absorbent zone in fluid communication with said capture zone.

18. The immunoassay device of claim 17, wherein said barrier zones comprise structural hydrogel.

19. The immunoassay device of claim 17, wherein said barrier zones comprise an enterosoluble coating.

20. The immunoassay device of claim 18, wherein said barrier zones comprise a biodegradable phospholipid.

21. An enzyme immunoassay device, comprising:
a sample pad containing a first enzyme and a second enzyme, said second enzyme conjugated to a first antibody having affinity for an analyte;
a label pad in fluid communication with said sample pad, said label pad containing a substrate for said first enzyme, wherein said substrate for said first enzyme is converted by said first enzyme to a second substrate for said second enzyme;
a capture zone in fluid communication with said label pad, said capture zone containing a second antibody having affinity for said analyte at a test line, wherein said second substrate is converted by said first antibody to an enzyme product; and
an absorbent zone in fluid communication with said capture zone.

22. The immunoassay of claim 21, wherein said first enzyme is selected from the group consisting of alkaline phosphatase, esterase, protease, sulfatase, chymotrypsin-like protease, creatine amidinohydrolase and arginase.

23. The immunoassay of claim 21, wherein said second enzyme is selected from the group consisting of β -D-galactosidase, N-acetylglucosaminidase, α -L-arabinofuranosidase, exglucanase, chitobiosidase, α -L-fucosidase, β -D-glycosidase, α -galactosidase, β -glucosidase, glucansucrase, β -D-glucuronidase, α -amylase, α -mannosidase and β -mannosidase.

24. The immunoassay of claim 21, wherein said analyte is selected from the group consisting of hormones, enzymes, lipoproteins, bacterial or viral antigens, immunoglobulins, lymphokines, cytokines, drugs and soluble cancer antigens.

25. A sample receiving layer for use in an enzyme immunoassay device, comprising: a disk comprising inner and outer hydrophilic zones separated by a hydrophobic barrier, said inner zone containing an enzyme substrate and having a smaller pore size than said outer zone, said outer zone containing an enzyme-antibody conjugate having affinity for an analyte.